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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,649	10/27/2003	Hanson S. Gifford III	020979-002310US	3982

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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10/24/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/695,649

Applicant(s)

GIFFORD ET AL.

Examiner

MICHAEL KAHLIN

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14, 18-20 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
3. Claims 11, 14, 18,-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger (US 6,193,648, hereinafter "Krueger").
4. In regards to claim 11, Krueger discloses a method for treating congestive heart failure (col. 3, ln. 43) comprising placing a band having a first and second end with a gap around a beating heart (Fig. 6) and drawing the first and second ends of the band together with a supporting spring member that spans the gap (30, 34, 32, and 35). Please note that the "supporting spring member" is being interpreted as the entire suture/spring assembly. Krueger does not disclose that the supporting member has a

biodegradable element which delays the first and second end of the band from drawing together for a preselected time after placing the band around the heart. It is well known in the cardiac constraint device art to provide supporting members that have a biodegradable element which delays the first and second ends of the band from drawing together for a preselected time after placing the band around the heart to provide the predictable results of allowing easy implantation and encourage continued reverse remodeling of the heart. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by providing supporting members that have a biodegradable element which delays the first and second ends of the band from drawing together for a preselected time after placing the band around the heart to provide the predictable results of allowing easy implantation and encourage continued reverse remodeling of the heart.

5. In regards to claim 14, Krueger discloses that the supporting spring member is a spring under tension between the first and second ends of the band (Figs. 6 and 7).

6. In regards to claims 18 and 19, the band is introduced to the heart and at least a portion of the band is below the AV groove (Fig. 6).

7. Claims 20 and 22 are rejected under 35 U.S.C. 103(a) as obvious over Krueger. Krueger discloses the essential features of the claimed invention, including treating valvular disorders (abstract), but does not expressly disclose implanting with a subxiphoid approach or that the valvular disorder is mitral regurgitation. It is well known in the art to implant similar devices via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest, and treat such

valvular disorders as mitral regurgitation with bands such as Krueger's to provide the predictable result of constricting the heart in such a way as to avoid this undesired regurgitation of blood. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by implanting via a subxiphoid approach to provide the predictable results of implanting the device without the need to spread the chest, and treating such valvular disorders as mitral regurgitation to provide the predictable result of constricting the heart in such a way as to avoid this undesired regurgitation of blood.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krueger in view of McCarthy et al. (US 6,406,420, hereinafter "McCarthy"). Krueger discloses the essential features of the claimed invention except for ends located on and adhered to opposite sides of an infarcted region. McCarthy teaches a band device comprising ends located on opposite sides of an infarcted region (col. 6, ll. 39-63) to provide the predictable results of promoting reverse remodeling of this compromised tissue. Further, it is well known in the art to provide cardiac reinforcement bands adhered to the heart to provide the predictable result of preventing the jacket from shifting during therapy. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Krueger's invention by providing ends located on opposite sides of an infarcted region to provide the predictable results of promoting reverse remodeling of this compromised tissue, and a band adhered to the heart to provide the predictable result of preventing the jacket from shifting during therapy.

Response to Arguments

9. Applicant's arguments filed 6/17/2008 have been fully considered but they are not persuasive. Applicant argued that the "well-known" teaching of delaying the drawing of a support band with a biodegradable element is not of record, and if such teaching is cited, the resulting rejection should be made non-final to allow Applicant to address such rejection. However, an exemplary teaching of this feature was provided in the previous Office Action (See Shapland (US 6,425,856), specifically column 12, lines 3-37, cited in the "Conclusion" section of the Office Action of 4/25/2008). Additionally, although the subject matter of amended claim 11 contains limitations that were present in various previous dependent claims, there has not yet been presented a single claim that contained all the limitations of amended claim 11. For instance, claims 16 and 17 were both dependent on claim 15, thus the *combined* limitations of claims 16 and 17 constitute an amendment and any grounds of rejection in the present Office Action are necessitated by such amendment.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Michael Kahelin/
Examiner, Art Unit 3762